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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,127	07/30/2001	William J. Curatolo	PC10754AJTJ	1383

7590

02/23/2005

Gregg C. Benson
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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/918,127	Applicant(s) CURATOLO ET AL	
	Examiner Blessing M. Fubara	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-96 is/are pending in the application.
- 4a) Of the above claim(s) 11-16 and 19-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 17, 18 and 35-96 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

James M. Spear
JAMES M. SPEAR
 PRIMARY EXAMINER
AU 1615

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/22/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time filed 10/21/04; declaration under 37 CFR 1.131 by Douglas Lorenz filed 10/21/04; declaration under 37 CFR 1.132 by Drs. Dwayne T. Friesen and Dr. William J. Curatolo, filed 10/21/04; amendment and remarks filed 10/21/04; and IDS filed 11/22/04. Claims 1-96 are pending and of these, claims 11-16 and 19-34 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

1. The rejection of claims 49-55 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because applicants' argument is persuasive.

Claim Rejections - 35 USC § 102

2. Claims 2-10, 17, 18, 35-51, 56-86 and 88 remains rejected under 35 U.S.C. 102(b) as being anticipated by Sikorski (WO 99/14204). Claim 1 is withdrawn from the rejection since the amended claim does not recite hydroxypropylmethyl cellulose. This amendment gives rise to new rejection that will be discussed later.

3. Applicants' arguments filed 10/21/04 have been fully considered but they are not persuasive.

Regarding applicants' argument that Sikorski does not disclose solid amorphous dispersions as required by applicants, it is noted that Sikorski discloses a composition comprising cholesteryl ester transfer protein (CETP) inhibitor (page 4, line 30 to page 12 line 19). Furthermore, on page 84, lines 27-29, Sikorski discloses that active compound may be dispersed in hydroxypropylmethyl cellulose. Applicants' argument that Sikorski is a controlled release formulation, which does not generally increase the maximum concentration and/or bioavailability

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of a poorly soluble drug has been considered but that argument is not persuasive because the instant claims are directed to compositions that contain solid dispersions of low-solubility drugs in/with concentration enhancing polymers. The concentration enhancing polymers are as recited in claim 2 and hydroxypropylmethyl cellulose is one of the recited polymers. Sikorsky discloses a low-solubility drug, CETP dispersed in hydroxypropylmethyl cellulose. Powder is amorphous and the Remington article provided does not state that powders are not amorphous. The article provided discusses the means of producing powders and in first paragraph, left column, powders are categorized as finely divided solid materials. As for controlled release nature of Sikorski as analyzed by applicants, it is respectfully noted that the examined claims do not exclude controlled release formulations and controlled release is determined by the matrix excipients that make up the formulation. The claims are not directed to process of formulating the composition and the claims are not product by process claims so that the process of making the formulation would provide a product that is structurally different from the composition of Sikorski. **PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS.** Sikorski uses the term dispersion. On page 7 of the remarks, first full paragraph, applicants state that Sikorski does not disclose controlled release systems containing a solid amorphous dispersion and on page 6 of the remarks, applicants state; "Sikorski refers specifically to controlled release formulations." These two conflicting statements within the same document are confusing. However, the 132 declarations will be addressed below. Sikorski starts from a powder and powder is amorphous and Sikorski does not exclude amorphous drugs. The dependent claims include the elements of 1 or 2-4 as the case may be as is recited in the claims (see instant claims 5-10).

Declaration by Dr. Curatolo:

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Dr. Curatolo provides interpretation of the prior art in which Dr. Curatolo states that Sikorski refers in context to controlled release formulation when on page 84, lines 27-29, Sikorski discloses that “such capsules or tablets may contain a controlled release formulation as may be provided in a dispersion of active compound in hydroxypropylmethyl cellulose.” By this Dr. Curatolo appears to be stating that Sikorski discloses a controlled release formulation. Although, this may be the case, there is a disclosure that the active compound may be dispersed in hydroxypropylmethyl cellulose. The examined claims do not exclude controlled release and hydroxypropylmethyl cellulose is one of the polymers recited in the claims except for claim 1. Dr. Curatolo’s declaration centers on controlled release nature of Sikorski and the claims do not exclude controlled release or recite controlled release. The declaration for controlled release goes against what is discussed in the remarks at page 7. This interpretation is not persuasive especially when the claims have not excluded controlled release formulation.

Declaration by Dr. Friesen:

Dr. Friesen opines that Sikorski discloses controlled release formulation at page 84. This opinion appears to ignore the disclosure that the compound is dispersed in hydroxypropylmethyl cellulose, which is one of the polymers recited in claim 2. Even if Sikorski discloses controlled release, the claims have not excluded controlled release formulation.

The scope of paragraph 7 and exhibit 1 is not commensurate with the scope of claims that do not recite amounts of the concentration enhancing polymers and the amount of the drug. Sikorski does not disclose crystalline drug.

The scope of paragraph 8 differs from Sikorski because Dr. Friesen provides physical mixture of drug 2 with HPMC while Sikorski’s disclosure of dispersing the active compound in HPMC is ignored. Sikorski does not disclose physically mixing the active compound with

HPMC. The declaration is not commensurate with the broad claims where amounts of CETP and concentration enhancing are not recited.

Powder is an amorphous solid and applicants have provided no data showing the contrary that powder is not a solid or powder is not amorphous.

Examiner's remarks about spray drying is a statement intended to convey spray drying is a known method in the art for producing dispersion.

Declaration by Douglas Lorenz:

The 131 declaration antedates the Appel reference and thus Appel is removed as a reference.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 52-55, 87 and 89-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sikorski (WO 99/14204).

Sikorski has been discussed. Sikorski's composition is administered to subject in need thereof to treat conditions treatable with CETP's. The conditions recited in claims 89-96 are all conditions that are treatable with CETP. Spray drying is a known method in the art for producing dispersion or tablets or granules or pellets. Sikorski does not disclose the polymers recited in claim 1. One polymer can be substituted for another. And it is known in the art that hydroxypropylmethyl-cellulose, hydroxypropylmethylcellulose phthalate,

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hydroxypropylmethylcellulose acetate succinate, hydroxypropylmethylcellulose acetate phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, polyvinyl pyrrolidone, polyvinyl alcohol, and copolymers of polyvinyl pyrrolidone and polyvinyl alcohol are equivalent as dispersion polymers (Appel et al. US 6,706,283, claim 30 is a teaching reference).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to disperse CETP in hydroxypropylmethyl cellulose according to Sikorski. One having ordinary skill in the art would have been motivated to substitute hydroxypropylmethyl cellulose with hydroxypropylmethylcellulose phthalate, hydroxypropylmethylcellulose acetate succinate, hydroxypropylmethylcellulose acetate phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, polyvinyl pyrrolidone, polyvinyl alcohol, or copolymers of polyvinyl pyrrolidone and polyvinyl alcohol with the expectation of dispersing CETP.

No claim is allowed,

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bf

Blessing Fubara
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James M. Spear

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